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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,504	10/25/2001	Greg H. Lambrecht	INTRIN.001CP3	7447
20995	7590	09/07/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			BARRETT, THOMAS C	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,504

Applicant(s)

LAMBRECHT ET AL.

Examiner

Thomas C. Barrett

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-12, 14-22, 43-45 and 55-63 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 12-20, 23-42 and 48-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 21, 22, 43-47, 62 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-8, 10-12, 14-22, 43-45 and 55-63 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant argues that support for the added limitation, "wherein said nuclear augmentation material comprises a fluid that is incapable of changing phase in situ" can be found in the originally filed specification, including paragraphs 231-234. This argument has been fully considered but is not persuasive.

Paragraph 235 states:

The augmentation material 554 may remain "fluid" after the infusion step, or may polymerize, cure, or otherwise harden to a less flowable or nonflowable state.

However, the phrase "may remain fluid" is not equivalent to the limitation, "a fluid that is incapable of changing phase in situ."

The Applicant also states, "One of ordinary skill in the art would understand that many if not all, of these fluids simply cannot change phase in the disc environment. In other words, at body temperature, these fluids remain fluid." The Applicant has failed to supply evidence to support this statement. In addition, it is noted that the features upon which applicant relies (i.e. fluids remain fluid at body temperature) are not recited in the rejected claim(s). In addition there are other factors such as pressure and volume which may determine the phase of the fluid in the disc environment. Furthermore, claim 11 recites the limitation, "wherein said fluid is selected from the group..."

While a claim may be broader than a specific embodiment disclosed in the specification, the claims may be no broader than the supporting disclosure. Thus a

Art Unit: 3738

narrow disclosure will limit claim breadth. Therefore, even if the Applicant were to supply evidence regarding the disclosed fluids and their phase in the disc environment, it would still not be enough to demonstrate that the specification discloses the claimed broader invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11, 21-22, 44-47 and 62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The added limitation, "wherein said nuclear augmentation material comprises a fluid that is incapable of changing phase in situ" was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 63 is rejected under 35 U.S.C. 102(b) as being anticipated by Felt et al. (WO 97/26847). Felt et al. discloses an intervertebral disc system comprising an annulus augmentation device (first outer biomaterial) and a liquid nuclear augmentation material (page 11, lines 1-25). The fluid is capable of remaining as a liquid because the liquid may require “the application of a suitable energy source” to cure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (5,800,549) in view of Kamiya et al. (5,192,301), both as disclosed in Applicant's IDS. Bao et al. discloses an intervertebral disc system comprising at least one nuclear augmentation material (12) however Bao et al. fails to disclose an annulus augmentation device (or material). Kamiya et al. teaches a biocompatible plug for closing defects (e.g. figure 1). It would have been obvious to one of ordinary skill in the art to combine the teaching of a biocompatible plug for closing defects, as taught by Kamiya et al., to an intervertebral disc system as per Bao et al., the motivation to

combine being the plug can be used in percutaneous methods, as found in Kamiya et al. (col. 9, lines 1-3).

Claims 1-8, 11, 21-22, 44-47 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felt et al. (WO 97/26847) as above in view of Ray et al. (4,904,260). Felt et al. discloses an intervertebral disc system comprising an annulus augmentation device and a liquid nuclear augmentation material however Felt et al. fails to disclose the liquid as incapable of changing phase in situ. Ray et al. teaches an aqueous solution of a mucopolysaccharide such as hyaluronic acid (col. 5, lines 43-47), which is "incapable of changing phase in situ" as admitted by the Applicant in claim 11. It would have been obvious to one of ordinary skill in the art to combine the teaching of an aqueous solution of hyaluronic acid, as taught by Ray et al., to an intervertebral disc system as per Felt et al., the motivation to combine being the fluid has a viscosity and velocity-shear behavior imitating the natural rheology of intradiscal nuclear tissue, as found in Ray et al. (col. 5, lines 23-29).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. In addition, Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on July 6, 2005 prompted the new ground(s) of rejection presented in this Office action regarding claim 43. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Art Unit: 3738

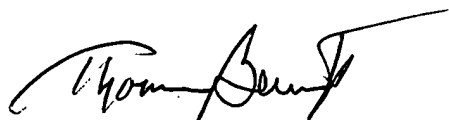
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett
Examiner
Art Unit: 3738